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The efficacy of intrapartum fetal surveillance when fetal pulse oximetry is added to cardiotocography

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Abstract

Objective: To determine if oxygen saturation measurement with pulse oximetry (SpO₂) in combination with cardiotocography (CTG), improves the assessment of the intrapartum fetal condition. **Study Design:** Four expert obstetricians individually evaluated 119 cases that were monitored during labor: during the first session the CTG data were available, and in the second session CTG and SpO₂ data were evaluated. They were instructed to indicate the need for intervention and to estimate the umbilical artery pH. **Results:** In the non-acidotic group (umbilical artery pH ≥ 7.15 , $n = 112$) the average (\pm S.D.) number of interventions decreased from 27 (± 17) to 16 (± 9) when SpO₂ was available. This reduction in number of interventions resulted in an significantly increased specificity for two referees. In the acidotic group ($n = 7$) the average number of interventions also decreased, from 6 (± 2) to 4 (± 2), and as a consequence the sensitivity decreased. The pH estimate based on CTG + SpO₂ was higher in both acidotic and non-acidotic fetuses than the estimated pH based on CTG alone. **Conclusion:** In this study all referees intervened less frequently when SpO₂ was used as an adjunct to CTG. This resulted in fewer unnecessary operative interventions, but may also lead to unidentified fetal acidosis. The number of acidotic newborns ($n = 7$) was too small, however, to draw definite conclusions. Larger studies should address the efficacy of SpO₂ in detecting fetal compromise before clinical use can be advocated. © 1997 Elsevier Science Ireland Ltd.

Keywords: Intrapartum fetal surveillance; Pulse oximetry; Sensitivity; Specificity

1. Introduction

Cardiotocography, although widely used, has not been shown to be a superior method of fetal surveillance during labor compared to intermittent auscultation. In fact, it leads to more obstetrical interventions without a clear benefit to the fetus [1]. Therefore fetal scalp blood sampling has been advocated to verify the

fetal condition when an unreassuring fetal heart rate pattern occurs [2]. This method has its drawbacks, requiring some operator skill and providing information about the fetal acid base balance only at the time of sampling. Fetal pulse oximetry (SpO₂) supplies information about the state of fetal oxygenation. It is non-traumatic, easy to apply and continuous, and has been shown to be a feasible technique to monitor the fetus during labor [3]. The accuracy of the method has been evaluated in fetal lamb studies [4–6]. The effect of SpO₂ monitoring on the assessment of the fetal condition has not been published.

The purpose of this study was to determine if the

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continuous measurement of fetal arterial oxygen saturation, as an adjunct to CTG, could improve the assessment of the fetal condition during labor, as compared to the use of CTG alone.

2. Materials and methods

Data for this study were collected in five centres, three in Europe and two in the United States. In all centres the study protocol was approved by the local ethical committee and maternal consent was obtained. A total of 308 singleton pregnancies between 37 and 42 weeks were monitored during labor with CTG and SpO₂. A specially designed fetal oximeter and a prototype reflectance sensor (wavelength 660/890 nm, Nellcor N400/FS10, Pleasanton, CA) were used [7]. After membranes were ruptured and cervical dilatation was at least 2–3 cm, the SpO₂ sensor was placed on the temple or cheek area of the fetal face. Adequate contact between sensor and fetal skin was measured by impedance. SpO₂ values were blinded to the clinicians managing labor. Clinical decisions were made on the basis of CTG alone or in combination with fetal blood sampling (depending on the hospital's routine). Cord blood samples (artery and vein) were taken immediately after delivery. All 308 recordings were stored digitally and sent to the University Hospital Nijmegen with case report forms. There they were printed out on standardized recording paper, with a paper speed of 1 and 3 cm/min. The cases were selected according to the following criteria: at least 45 min of continuous electronic fetal monitoring and SpO₂ monitoring, and a maximum interval of 15 min between removal of the sensor and birth. This resulted in 119 cases that were eligible for study.

Four referees — one from the USA, one from the

UK, one from Germany and one from The Netherlands, all not involved in the organization of the study, were invited for a meeting held in Nijmegen, The Netherlands. The referees, all experienced obstetricians, were informed about fetal pulse oximetry and results from clinical and animal studies. They all agreed that a SpO₂ value of 30% was the lower limit of fetal aerobic metabolism. Clinical information that may influence the fetal heart rate pattern or the fetal condition were given (maternal age, parity, gestational age, highest temperature during delivery, medication, oxygen, anaesthesia, meconium, duration stage 1, time start stage 2, actual neonatal weight). No information was provided on obstetric management or fetal outcome. On the first day, the referees received randomly numbered envelopes, each containing an CTG monitoring strip (with the paper speed of their preference), case information and a questionnaire. They were individually instructed to evaluate the intrapartum fetal condition and indicate the need for intervention, when they diagnosed fetal compromise. The referee was also asked to give an estimate of the umbilical artery pH, divided in seven classes of 0.05 increments ranging from < 6.98 (6.98–7.02) etc. to > 7.22.

In the second session, the next day, the envelopes contained a monitoring strip with the fetal heart rate, the uterine activity and the SpO₂ (Fig. 1). Included again were case information and their judgement from the first day. They were asked again to intervene when fetal compromise was likely and to predict the umbilical artery pH. The referees were informed of their positions in the first round, to avoid intra-observer variability. In this way, changes in assessment of the fetal condition only resulted from the information deducted from SpO₂.

For the analysis of the data the actual neonatal

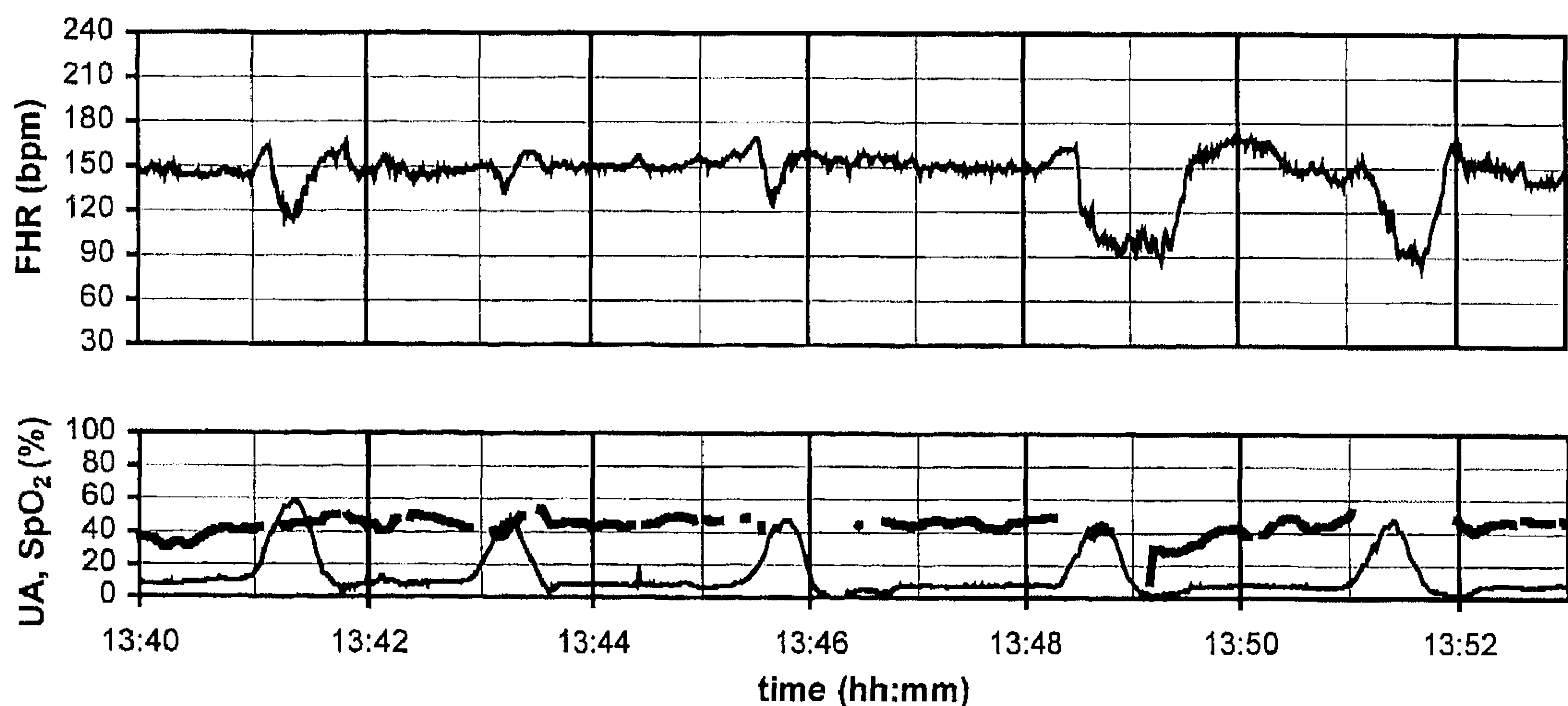


Fig. 1. Simultaneous recording of fetal heart rate (FHR), uterine activity (UA) and fetal arterial oxygen saturation (SpO₂) estimated with pulse oximetry.

outcome (umbilical artery pH) was related to the opinion of the referee concerning the need for intervention based on CTG and CTG combined with SpO₂. For this assessment acidosis was defined as an umbilical artery pH < 7.15, which is the tenth centile of the population delivered from 1978 to 1980 in the University Hospital Nijmegen [8]. The results for both diagnostic techniques were summarized in terms of sensitivity and specificity. Sensitivity (the proportion of correctly classified acidotic newborns) and specificity (the proportion of correctly classified non-acidotic newborns) of the diagnosis, 'fetal compromise, intervention needed,' were determined for each referee. The accuracy of pH estimation in the umbilical artery was evaluated by the difference between the estimated pH and actual pH (Δ pH). Differences between the interventions and pH estimates, based on CTG and CTG + SpO₂, were tested for significance with the McNemar test and sign test. For small numbers the exact binomial distribution was used. A *P*-value < 0.05 was considered significant.

3. Results

From 308 monitored cases, 47 cases (15.3%) were excluded because no simultaneous monitoring with CTG and SpO₂ was available until birth. In 142 cases (46.1%) the interval between removal of the sensor and delivery was greater than 15 min. This resulted in 119 recordings that were eligible for use in this study. In Table 1 the proportion of Caesarean sections and vaginal operative deliveries and spontaneous deliveries in the total and the selected population are shown. From Table 1 it is clear that operative deliveries are underrepresented in the selected population, especially Caesarean section. From the 42 C-sections, in the total population, 6 were performed for fetal distress and 36 for failure to progress. Of the six for fetal distress, three were included in the study. The overall intervention rate in the 308 monitored cases was 43% and 27% in the selected population.

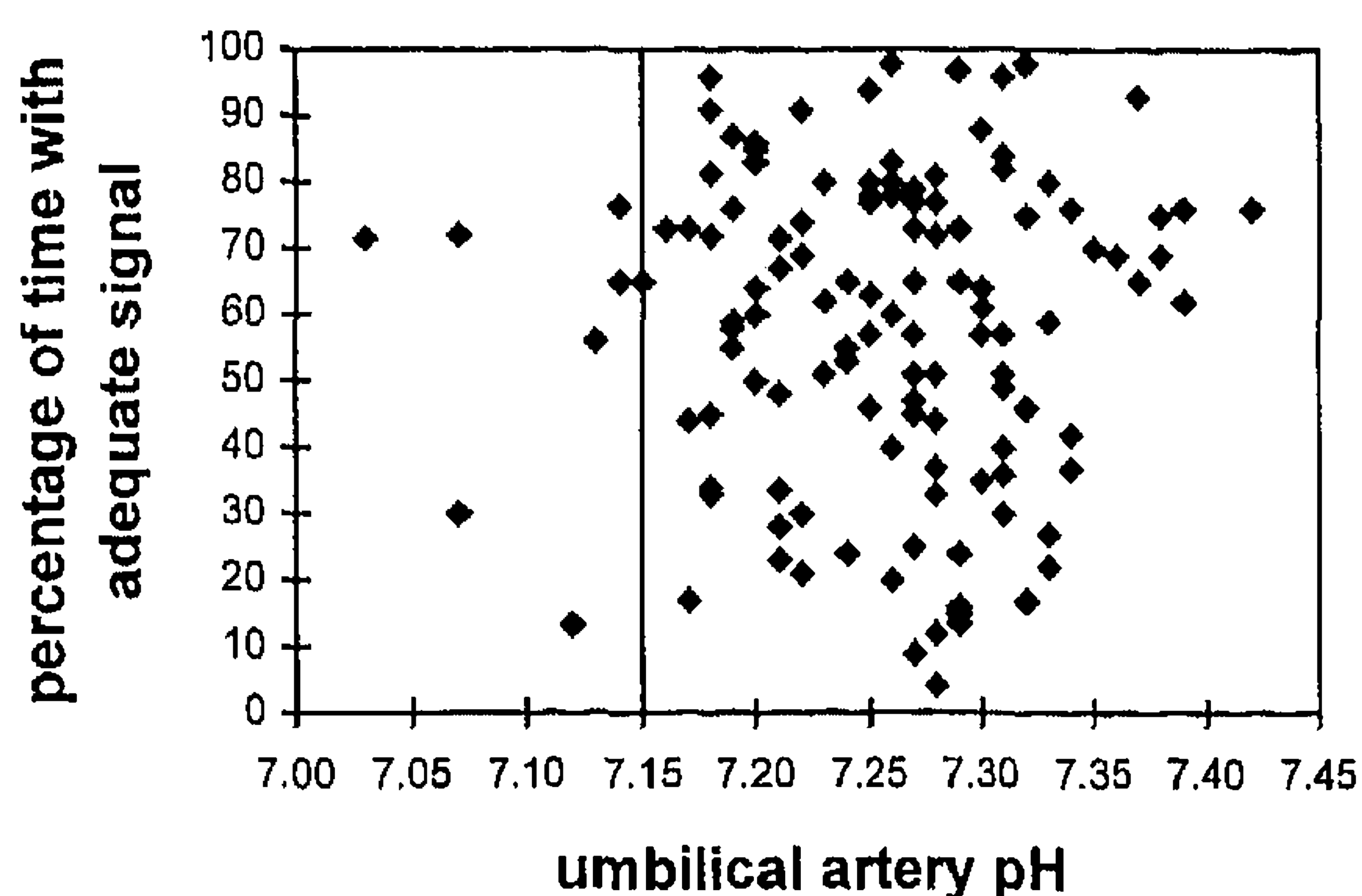


Fig. 2. Percentage of adequate SpO₂ signal in the group of selected bases in relation to umbilical artery pH.

Table 1

Mode of delivery in all cases and in those included in the study

	Spontaneous (%)	Vaginal operative (%)	Cesarean section (%)
All cases (<i>n</i> = 308)	57	29	14
Study population (<i>n</i> = 119)	73	24	3

The mean umbilical artery pH was 7.26, both in the selected group (*n* = 119) and in the total population (*n* = 308). The total population contained 12 cases with an umbilical artery pH < 7.15. From the 119 selected cases, the percentage of recording time with adequate SpO₂ signal is shown in Fig. 2. In the acidotic group (pH < 7.15, *n* = 7) the median percentage of adequate signal was 65% with a range of (14–76%). In the non-acidotic group (pH ≥ 7.15, *n* = 112) the median was 62% (4–98%).

The average number of interventions (\pm S.D.) as indicated by the referees in the non-acidotic group (*n* = 112) was 27(\pm 17) or 24.1% based on electronic fetal monitoring, and 16(\pm 9) or 14.3% when SpO₂ was added. The reduction in number of interventions resulted in an increased specificity for all referees. This was significant (*P* < 0.001) for two referees (Table 2). In the acidotic group the average number of interventions also decreased. The sensitivity decreased for three of the four referees but no significance at a *P* < 0.05 level was reached. The acidotic group consisted of only seven cases. The average specificity and sensitivity of the four referees based on CTG and CTG combined with SpO₂ is shown in Fig. 3.

The four referees changed in 9–45% of the cases their estimated pH; for all referees these changes were in almost all cases in the direction of the prediction of a better fetal condition (Table 3). Three of the four referees changed their opinion significantly. In the non-acidotic group the estimated pH was closer to the actual value after addition of the SpO₂ informa-

Table 2

Sensitivity and specificity of the diagnosis, 'Fetal compromise likely, intervention needed', based on CTG and CTG combined with SpO₂, determined for each referee. Sensitivity and specificity are expressed as percentages (with 95% confidence intervals)

Referee	Sensitivity		Specificity	
	CTG	CTG + SpO ₂	CTG	CTG + SpO ₂
A	86 (42–100)	86 (42–100)	80 (72–87)	84 (76–90)
B	100 (59–100)	43 (10–82)	80 (72–87)	90 (83–95)*
C	100 (59–100)	71 (29–96)	54 (45–64)	75 (66–83)*
D	43 (10–82)	0 (0–41)	88 (81–94)	93 (86–97)

**P* = < 0.001

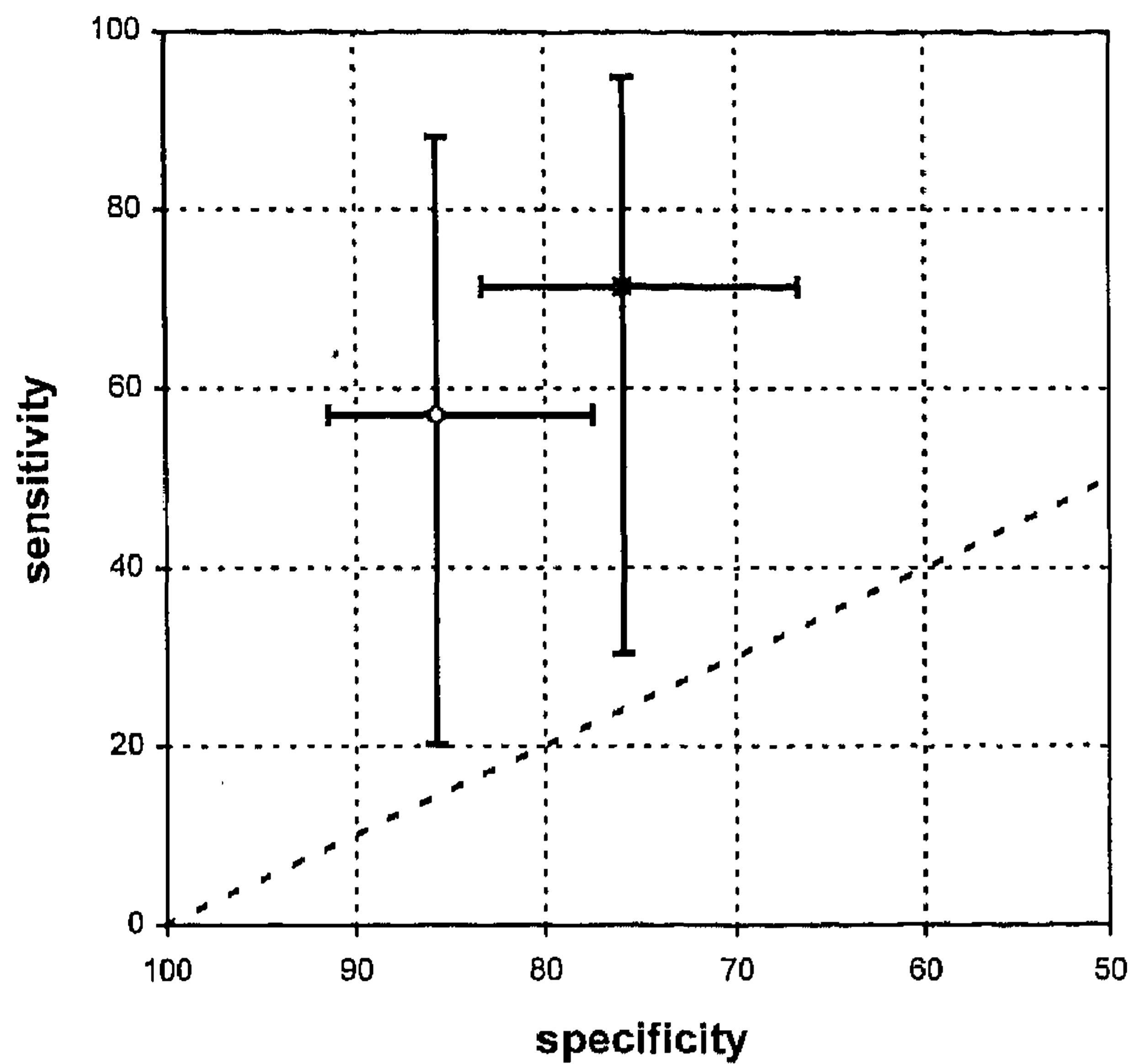


Fig. 3. Average validity for the four referees, with 95% confidence intervals. Filled square, based on CTG; open circle, based on CTG + SpO₂; dashed line, line of identity identifying a useless test.

tion: the number of improved pH estimates was greater than the number of less accurate estimates (Table 4).

4. Comment

There is an urgent need for non-invasive fetal monitoring techniques because the efficacy of current techniques is low. However, before a new technology should be allowed in the labour room, it has to be investigated for safety and accuracy, and the method should be evaluated to confirm improved assessment of the fetal condition leading to a greater sensitivity and specificity.

The accuracy of reflectance pulse oximetry cannot be investigated in the human fetus because arterial blood samples cannot be obtained. In fetal lamb studies, Jongsma et al. [4] and Harris et al. [5] published calibration curves and showed good correlations (precision of 4.7–6.6%; the precision is the expression of the standard deviation of the difference between the SpO₂ and sample SaO₂) over the range

Table 3

Influence of the addition of SpO₂ on the percentages of changed pH estimates and on the direction of the change, determined for each referee

Referee	Changed pH estimates (%)	pH estimate higher (%)	pH estimate lower (%)	Sign test P-value
A	9.2	6.7	2.5	ns
B	45.4	41.2	4.2	< 0.001
C	21.6	19	2.6	< 0.001
D	25.2	19.3	5.9	< 0.01

ns, not significant.

from 10 to 80% arterial oxygen saturation, using equipment similar to that in the study. Recently Nijland et al. [6] reported larger discrepancies between the readings of the oximeter and the arterial oxygen saturation values measured in the blood sample (precision 12.9%).

The present study is the first that investigates the effect of this new technique on the assessment of the fetal well-being during labor. In this study a paired comparison is made between CTG and CTG combined with SpO₂. Four referees were asked their opinions about the fetal condition based on electronic fetal monitoring and subsequently, if this opinion was changed by adding the SpO₂. Thus, intra-observer variability has to be considered. Lotgering et al. [9] and Nielsen et al. [10] showed that there is a large discrepancy in the level of agreement, within one observer, in judging the same fetal heart rate pattern. Because in this study the effect of SpO₂ on the interpretation of the fetal heart rate pattern was the primary goal, intra-observer-variability concerning the fetal heart rate was avoided by informing the referee of his position in the first session.

The fetal heart rate is regarded as a sensitive measure of fetal well-being. However, an unreassuring fetal heart rate pattern has a poor predictive value for fetal compromise. The results of this study are in agreement with this statement. Based on CTG, the referees correctly identified the acidotic fetuses to a high extent, but many unnecessary interventions were performed in non-acidotic fetuses.

Table 4

Number of improved and less accurate pH estimates in relation to the actual pH when SpO₂ is added, for the acidotic and the non-acidotic group separately, determined for each referee

Referee	pH < 7.15 (n = 7)			pH ≥ 7.15 (n = 112)		
	Improved pH	Less accurate pH	McNemar P-value	Improved pH	Less accurate pH	McNemar P-value
A	1	0	ns	5	4	ns
B	1	5	ns	34	11	< 0.01
C	0	4	ns	17	6	< 0.05
D	0	6	< 0.05	14	11	ns

All referees intervened less when SpO₂ was added to CTG monitoring. This resulted in fewer unnecessary interventions but also in fewer identified acidotic fetuses. In other words specificity improved, whereas sensitivity decreased. Only if sensitivity had remained the same one could conclude that combined surveillance with CTG and SpO₂ is a superior diagnostic tool. In fact the 'average validity that was calculated' could lie on the same receiver operating characteristic curve as CTG alone (see Fig. 3).

The influence of SpO₂ on the estimation of the umbilical artery pH was different among the four referees. Changes in opinion ranged from 9.2 to 45.4%. It is noteworthy that in the majority of cases (85%) a higher pH was predicted if SpO₂ data were available. Therefore the accuracy of the estimated pH improved for non-acidotic (pH \geq 7.15), and worsened in the acidotic neonates.

The misjudgement of the acidotic fetuses when SpO₂ is added may be caused by signal loss. Using the same technique, Dildy [7] reported an average percentage of 50–60% adequate signal acquisition during the first and second stage of labor, which is in agreement with the findings in this study. The amount of signal loss did not differ between the non-acidotic and acidotic group (see Fig. 2). However, especially during contractions, when diminished placental perfusion may cause oxygen desaturation, signal loss often occurred. Therefore the referees may have been falsely reassured by SpO₂ levels above 30% when registration was available, and the amount of adequate signal may have been too low to identify fetuses at risk.

An SpO₂ of 30% has been shown to be the lower limit to prevent anaerobic glycolysis in the fetal lamb [11,12]. The critical SpO₂ value in the human fetus is not known. In a multi centre study, Dildy et al. [13] reported a wide range of SpO₂ values (30–81%) in the human fetus with normal outcome. In fetuses with abnormal delivery and outcome, such as unreassuring fetal heart rate, low Apgars and low umbilical artery pH, the average saturation did not appear to be lower. Signal loss may be the cause of a falsely elevated average SpO₂ value.

Furthermore one could argue that the chosen cut-off value used to define fetal acidosis (pH < 7.15) is too high. A lower threshold may show a more accurate identification of the acidotic fetuses when SpO₂ is used. In the current study a lower cut-off value, for instance pH 7.10, would result in only three acidotic cases.

The principal goal of using fetal pulse oximetry as an adjunct to electronic fetal monitoring is to improve the specificity of fetal surveillance (less unnecessary obstetric interventions). This study is encouraging because the specificity for predicting fetal compromise

was improved by adding SpO₂. However, we cannot conclude that combining SpO₂ with CTG improves the prediction of poor fetal condition, because the number of acidotic fetuses was too small. Larger studies should address the efficacy of SpO₂ in detecting fetal compromise before clinical use can be advocated.

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